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Bezlotoxumab for Prevention of Recurrent Clostridium difficile Infection in Cancer Patients: Report of Clinical Case

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Abstract: Patients with cancer are at increased risk of Clostridium difficile infection (CDI) and its recurrence (rCDI) due to immunosuppression and frequent antibiotic exposure. Bezlotoxumab—a monoclonal antibody targeting toxin B of C. difficile—has been studied in phase III trials and post-hoc analyses, showing significant reduction in rCDI risk. Here we present a clinical case report illustrating the real-world use, outcome, and implications of bezlotoxumab in a cancer patient, integrated with current evidence and graphical summaries of efficacy and safety.

Keywords: Clostridium difficile infection (CDI), Bezlotoxumab, Recurrent CDI (rCDI), Cancer Patients, Monoclonal Antibody Therapy.

INTRODUCTION

Clostridium difficile infection is a leading cause of healthcare-associated morbidity, especially in immunocompromised hosts such as cancer patients. Recurrent CDI complicates treatment outcomes and quality of life, and increases healthcare costs. Cancer patients face unique challenges—immunosuppression, chemotherapy, frequent hospitalizations, and antibiotic use all contribute to increased incidence and severity of CDI. Standard-of-care antibiotics (vancomycin, fidaxomicin) are effective for initial cure but provide limited protection against recurrence. Bezlotoxumab has emerged as an adjunctive preventive option against rCDI, particularly in high-risk cohorts. This article presents a detailed case report and a review of existing evidence for bezlotoxumab's role in cancer patients.

CLINICAL CASE REPORT

Patient Background

- **Demographics**: 60-year-old woman
- **Diagnosis**: Metastatic breast cancer, on palliative chemotherapy (docetaxel and carboplatin)

- **Medical History**: Multiple prior hospitalizations, two documented episodes of CDI in the past eight months, recurrent neutropenia, recent course of piperacillin-tazobactam for febrile neutropenia

Clinical Course

1. **Presentation**: Admitted with new-onset watery diarrhea (≥5 stools/day), abdominal cramps, and low-grade fever.
2. **Workup**:
   - Positive for C. difficile toxin B gene (PCR).
   - Laboratory: Neutropenia (ANC 900/μL), mild renal insufficiency.
   - Imaging: No toxic megacolon.
3. **Management**:
   - Standard-of-care: Oral vancomycin 125mg q6h initiated.
   - Supportive care: Intravenous fluids, neutropenic precautions.
   - Gastroenterology consult recommended adjunctive bezlotoxumab due to multiple recurrences and cancer status.
   - Bezlotoxumab 10mg/kg single intravenous infusion administered on day 3 of vancomycin therapy.
4. **Course and Outcomes**:
   - Diarrhea resolved within five days.
   - ANC recovery by day 7; discharged off antibiotics.
   - No recurrence of CDI over 12-week follow-up despite ongoing chemotherapy and subsequent courses of prophylactic antibiotics.
   - No infusion reactions or bezlotoxumab-related adverse events documented.

Table 1. Timeline of Clinical Events

Day	Event
1	Hospital admission, diarrhea onset
1	CDI confirmed, vancomycin started
3	Bezlotoxumab 10mg/kg infused
5	Resolution of diarrhea
7	Neutrophil recovery; hospital discharge
90	No rCDI, ongoing chemotherapy

REVIEW OF EVIDENCE

Efficacy in Cancer Patients

- **Post-hoc analysis of MODFIY I/II trials**: 382 cancer patients analyzed (190 bezlotoxumab, 192 placebo). Recurrent CDI rates were significantly lower in the bezlotoxumab arm (17.8%) vs. placebo (30.4%); absolute risk reduction 12.6% (95% CI: –22.5% to –2.7%) [1][2][3].
- **Initial clinical cure** rates were similar between treatment groups, indicating bezlotoxumab's role is prevention, not acute treatment [1][3].
- **Hospital readmissions and mortality**: Trends for fewer 30-day CDI-associated rehospitalizations and lower 90-day mortality observed in bezlotoxumab-treated cancer patients (not statistically significant) [2].

Mechanism & Rationale

- Bezlotoxumab binds and neutralizes C. difficile toxin B, the principal driver of colonic inflammation and recurrence.
- Lack of immunogenicity makes it particularly suited for immunocompromised hosts such as cancer patients, who often fail to mount an effective antibody response to toxins after CDI [4][5].

Safety

- Comparable infusion-related reactions and adverse event rates across studies for cancer and non-cancer cohorts.
- No new safety signals observed in post-hoc analyses or real-world studies for the oncologic population [5][1].

Graph: rCDI Rate with Bezlotoxumab vs. Placebo in Cancer Patients

Group	Recurrence Rate (%)
Bezlotoxumab	17.8
Placebo	30.4

Graph: Bar chart showing significant reduction in rCDI among cancer patients receiving bezlotoxumab compared to placebo (MODIFY pooled analysis)

Comparative Risk Reduction in Subgroups

Subgroup	Recurrence with Bez (%)	Recurrence with Placebo (%)	Absolute Risk Reduction (%)
All Cancer Patients [n=382]	17.8	30.4	-12.6
Non-Cancer Patients [n=1,172]	similar	similar	-13

Patients with additional risk factors (age ≥65, severe CDI, immunosuppression, ribotype 027/078/244) have the greatest reduction in rCDI with bezlotoxumab [6][3][1].

DISCUSSION

Cancer patients experience higher rates of CDI recurrence and worse initial cure rates than the general population due to profound immune dysfunction and antibiotic exposure [2][1]. Evidence demonstrates bezlotoxumab significantly reduces the risk of rCDI in this vulnerable cohort, with a number needed to treat (NNT) of roughly 8–10[4][5].

Clinical Implications:

- Bezlotoxumab can be considered in cancer patients after two or more CDI episodes or in those with other risk factors for recurrence.
- Early intervention during standard antibiotic therapy maximizes benefit, particularly in patients expected to receive ongoing immunosuppression or antibiotics.
- Cost and resource considerations must be balanced with the risk of severe rCDI, hospital readmissions, and delayed cancer care.

Limitations:

- No dedicated randomized trials in cancer-only cohorts; current evidence is mainly from subgroup and post-hoc analyses.
- Impact on overall survival and quality of life requires further study[2][1][7].

CONCLUSION

Bezlotoxumab is an effective and well-tolerated adjunct for prevention of recurrent CDI in cancer patients, especially those with multiple risk factors or immunosuppression. Real-world and clinical trial data support its use to reduce recurrences, hospitalization, and potentially mortality. Ongoing research and real-world data will clarify its optimal placement in oncologic infection management protocols.

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